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April 5, 2024

By ECF

Hon. Jesse M. Furman
United States District Court for the
Southern District of New York
40 Foley Square
New York, New York 10007

The motion to seal is granted temporarily. The Court will assess whether to keep the materials at issue sealed or redacted when deciding the underlying motion. To the extent that UMB or any third party believes that the materials should be unsealed sooner, it shall file a letter motion, not to exceed three pages, seeking such relief.

SO ORDERED. April 8, 2024

Re: UMB Bank, N.A. v. Bristol-Myers Squibb Company, No. 21 Civ. 4897 (JMF)

Dear Judge Furman:

On behalf of defendant Bristol-Myers Squibb Company ("BMS"), I am writing pursuant to Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, Local Civil Rule 37.2, and sections 2(c) and 7(B) of the Court's individual practices to request that the Court enter an order to maintain under seal, until 14 days after the deadline for filing motions for summary judgment, the confidential merits discovery material ("Merits Discovery Materials") cited or quoted by plaintiff UMB Bank, N.A. ("UMB") in its opposition [ECF No. 95] to BMS's motion to dismiss for lack of subject matter jurisdiction [ECF No. 73]. The parties have conferred about the issue, and UMB has informed us it opposes the requested relief.

In their submissions, both parties have cited or discussed discovery materials designated confidential under the Stipulation and Order Governing Confidentiality of Discovery Materials and Preservation of Privilege that was entered on August 9, 2022 [ECF No. 41]. Both parties filed letter motions in accordance with section 7(C) of the Court's individual practices requesting that the confidential discovery materials they included be filed under seal, which the Court granted temporarily until the subject matter jurisdiction motion is resolved. [ECF Nos. 78, 99].

The Merits Discovery Materials are a fraction of the confidential discovery materials cited by UMB in its opposition. They are discussed on pages 3 and 6-8 of the opposition, in the "Background" section. They are not cited or discussed in any of UMB's legal arguments concerning its capacity to sue. Opp. at 12-24. Nor are they discussed in any of the BMS submissions. That is because none of the Merits Discovery Materials relate to the subject matter jurisdiction motion, which turns on UMB's putative appointment as trustee.

UMB's summary of the merits in its opposition is also misleadingly incomplete. Out of a massive discovery record, it relies on a handful of emails, chats, other documents, and a page or two of testimony plucked from the depositions of 15 different witnesses.[1] The full record will establish, whenever the breach of contract claims against BMS are adjudicated by a court with jurisdiction, that BMS far exceeded any potentially applicable standard in pursuing FDA approval of liso-cel by the contractual milestone date under the CVR Agreement – amidst the worst pandemic in a century – and that the FDA failed to act on the application by that date *in spite of* BMS's efforts, not because of any lack of effort.

But BMS will not compound UMB's misuse of confidential merits discovery materials to make the point now. Instead, even a review of public FDA materials establishes it. For example, UMB's attempt to blame BMS for delays based on an allegedly deficient biologics license application is belied by the FDA's own minutes of, and pre-meeting materials for, the late-cycle meeting for liso-cel on September 2, 2020, which show that: (i) by then, completing inspections of two liso-cel manufacturing facilities was the only remaining substantive review issue; (ii) the two inspections had not been scheduled yet solely because of FDA safety concerns about COVID-19; and (iii) the FDA was not willing to consider alternative (safer) approaches to the inspections that BMS developed and proposed.[2] Later FDA memos show that the inspections were the only item open as of the PDUFA action date, November 16, 2020, and that the FDA could not act on the application by that deadline only because of the pandemic.[3] When the FDA finally did conduct the inspections, including one only a few weeks before the liso-cel milestone date, its observations were limited ("voluntary action indicated") and, in the FDA's view, BMS responded promptly and adequately.[4]

A moment may arrive when the parties' competing views of the merits, based on a complete discovery record, will be adjudicated by a court with jurisdiction to do so. But that moment is not now. For the motion before the Court now, the Merits Discovery Materials are not "relevant to the performance of the judicial function and useful to the judicial process." *Lugosch v. Pyramid Co. of Onandaga*, 435 F.3d 110, 119 (2d Cir. 2006) (quoting *United States v. Amodeo*, 44 F.3d 141, 145 (2d Cir. 1995)). The materials therefore are not "judicial documents" to which a presumption of public access applies. *See id.* at 119 ("the mere filing of a paper or document with

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[1] In total, the Merits Discovery Materials comprise 19 exhibits and very limited excerpts from 15 depositions (74 transcript pages in total). *See* Declaration of Joshua S. Margolin dated March 15, 2024, Exhs. 1-19 [ECF No. 96]; UMB Opp. at 3, 6-8. In comparison to these limited citations, BMS produced a total of 20,173,235 pages of documents and 22 deponents (many of whom were former employees), who testified in the aggregate for more than 125 hours.

[2] All cited materials are available at https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/breyanzi-lisocabtagene-maraleucel; *see* Late-Cycle Meeting Mem., Oct. 1, 2020, at 4, and Late-Cycle Meeting Materials, Aug. 21, 2020, at 2-3.

[3] Division of Manufacturing and Product Quality ("DMPQ"), Adden. Review Mem., at 4.

[4] Summary Basis for Reg. Action, Feb. 5, 2021, at 10-11; DMPQ Adden. Review Mem. at 7, 8.

the court is insufficient"). Moreover, even if the Merits Discovery Materials could be deemed "judicial documents," the weight of any presumption of public access is low at this stage, because the materials will play, at most, "a negligible role in the performance" of this Court's "Article III duties." *Lugosch*, 435 F.3d at 121 (quoting *United States v. Amodeo*, 71 F.3d 1044, 1050 (2d Cir. 1995)).

The Court therefore should maintain a sealing order with respect to these materials until there is an "adjudication," such as a motion or motions for summary judgment, for which they are actually relevant. *See In re Allergan PLC Sec. Litig.*, 2020 WL 5796763, at 13 (S.D.N.Y. Sept. 29, 2020) (maintaining seal until summary judgment for confidential documents, including regulatory communications relating to breast implants, that were not relevant to class certification motion).

Further, the Merits Discovery Materials are not the type of information "historically open to the press and general public." *Lugosch*, 435 F.3d at 120 (citation omitted). To the contrary, both BMS and the FDA maintain the confidentiality of communications relating to applications for approval of a new biologics product candidate, which may involve confidential patient information, confidential regulatory communications and strategy, proprietary methods, and trade secrets, among other protected information, the disclosure of which could cause BMS competitive harm. *See In re Incretin-Based Therapies Products Liability Litigation*, 2021 WL 873290 (S.D. Cal. Mar. 9, 2021) (sealing FDA communications, clinical and non-clinical study materials, and other confidential regulatory strategy materials); *Williams-Roberts v. Coloplast Corp.*, 2021 WL 3570707 (N.D. Ind. Feb. 18, 2021) (in pelvic mesh action, sealing filings that included confidential FDA communications and trade secrets).

Courts also have recognized that selective disclosure out of context of confidential FDA materials, as in the UMB opposition, would be more likely to "mislead the public" about liso-cel than to "serve a general interest in public health or access." *Incretin-Based Therapies*, 2021 WL 873290, at *3. Liso-cel is an approved autologous cell therapy that is being administered to cancer patients now. Indeed, the FDA recently expanded its approval of liso-cel for use for additional indications. Permitting disclosure of the Merits Discovery Materials, without the context that will be provided by countervailing facts as in a fully briefed adjudication, could mislead and give rise to concerns about liso-cel among patients and care providers that are entirely unwarranted.

BMS therefore respectfully requests that the Court enter an order maintaining under seal the Merits Discovery Materials, and the portions of UMB's opposition brief discussing those materials, until 14 days after the deadline for filing summary judgment briefs in this action, when the issue can be considered again based on the procedural circumstances that then exist.

Respectfully submitted,

DLA PIPER LLP (US)

/s/ John J. Clarke, Jr.

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